UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,610	02/12/2001	Jonathan Stanley Harold Denyer	102199-100	3883

7590 09/13/2002

William A. Simons
Intellectual Property Law Section
WIGGIN & DANA
One Century Tower
New Haven, CT 06508-1832

EXAMINER	
MENDOZA, MICHAEL G	
ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 09/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/781,610	DENYER ET AL.	
	Examiner	Art Unit	
	Michael G. Mendoza	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 February 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5,6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "5" has been used to designate both a button and a data carrier. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: Reference number 5 is used to specify both a button and a data carrier.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 recites the limitation "the drug delivery apparatus" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 28 recites the limitation "the repeat prescription re-ordering portion" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-8, 12-14, 16, 17, and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolf et al. 5,505,195.

8. As to claim 1, Wolf et al. teaches a drug package comprising:

A plurality of drug vials 623 containing drugs for delivery to a patient in a drug delivery

device; and

a data carrier 110 including drug treatment information for use by the drug delivery apparatus (see abstract, lines 7-13).

9. As to claim 2, Wolf et al. teaches a drug package according to claim 1, wherein the data carrier is arranged to include at least one of the following items of treatment information:

a. the dose of drug to be delivered;

b. the identity of the drug which is to be delivered;

c. the expiry date of the drug to be delivered; and

d. the number of treatments available from the drug package (col. 13, lines 55-61).

10. As to claim 3, Wolf et al. teaches a drug package according to claim 1, wherein the drug vials contain drugs adapted for delivery in air inhaled by a patient to their lungs (col. 3, line 4-6).

11. As to claim 4, Wolf et al. teaches a drug package according to claim 3, wherein the drug vials are arranged to be used in conjunction with a drug delivery device for delivering the drug in the inhaled airstream of a patient (see abstract, lines 1-3).

12. As to claim 5, Wolf et al. teaches a drug package according to claim 1, wherein the data carrier is an electronic data carrier is an electronic data carrier (col. 2, lines 48-54).

13. As to claim 6, Wolf et al. teaches a drug package according to claim 1, wherein the date carrier is arranged to transfer treatment information to a drug delivery apparatus when it is moved to a receptive surface or region of the drug delivery apparatus (col. 6, lines 15-20).

14. As to claim 7, Wolf et al. teaches a drug package according to claim 1, wherein the data carrier is arranged to supply drug treatment information to a drug delivery apparatus a number of times corresponding to the number of treatments available from the drug package, or to the number of vials included in the drug package (col. 13, lines 64-67).

15. As to claim 8, Wolf et al. teaches a drug package according to claim 1, wherein a single data carrier is included which includes the drug treatment information for each drug via (col. 13, lines 55-63)l.

16. As to claim 12, Wolf et al. teaches a drug package according to claim 1, wherein the data carrier includes a memory for recording information concerning treatments received from the drug delivery device.

17. As to claim 13, Wolf et al. teaches a drug delivery apparatus comprising:

a delivery portion 140 for delivering a drug to a patient;

an input 790 for receiving treatment information for each treatment to be delivered to a patient; and

a delivery controller for controlling the amount of drug delivered to a patient on the basis of the received treatment information (col. 11, lines 41-65).

18. As to claim 14, Wolf et al. teaches a drug delivery apparatus according to claim 13, wherein the input is an electronic input which received the treatment information from an electronic data carrier (col. 10, lines 34-36).

19. As to claim 16, Wolf et al. teaches a drug delivery apparatus according to claim 14, wherein the input is additionally arranged to transmit completed treatment information to the data carrier for recordal (col. 13, lines 52-55).

20. As to claim 17, Wolf et al. teaches a drug delivery apparatus according to claim 13, wherein the drug delivery apparatus includes an authorization portion which prevents delivery if any of the treatment information indicates that the drug is unsuitable for delivery (col. 11, lines 24-34).

21. As to claim 19, Wolf et al. teaches an electronic data carrier for use with a drug delivery apparatus comprising a memory for holding treatment information concerning the use of the drug delivery apparatus in delivering a specified drug, and an output for transmitting treatment information to the drug delivery apparatus (col. 11, lines 52-54).

22. As to claim 20, Wolf et al. teaches a drug delivery system comprising:

A drug delivery apparatus for delivering a specified drug (fig. 6); and

an electronic data carrier 110 containing treatment information relating to the specified drug, the data carrier including an output for transmitting treatment information to the drug delivery apparatus before each treatment with the specified drug, whereby the drug delivery apparatus delivers the specified drug in conformity with the treatment information (col. 11, lines 41-64).

23. As to claim 21, Wolf et al. teaches a method of operating a drug delivery apparatus comprising:

supplying a plurality of vials 623 of a drug for use with the drug delivery apparatus;

supplying a data carrier 110 including treatment information;

transmitting treatment information from the data carrier to the drug delivery apparatus (col. 11, lines 41-64);

placing an amount of the drug from a vial in the drug delivery apparatus; and

delivering the drug in accordance with the treatment information from the data carrier (col. 3, lines 1-6).

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. Claims 9-11, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al. in view of Rode et al. 6,315,719.

26. As to claim 9, Wolf et al. teaches a drug package according to claim 1. It should be noted that Wolf et al. fails to teach wherein the data carrier is a radio frequency device. However, Rode et al. teaches wherein a data carrier is a radio frequency device (col. 3, lines 45-58). Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Wolf et al. to include the radio frequency device of Rode et al. to transmit information to a data logger or to a main system.

27. As to claim 10, Wolf/Rode teaches a drug package according to claim 9, wherein the data carrier is arranged to be powered from a magnet field associated with the drug delivery apparatus. It should be noted that Wolf/Rode fails to specifically teach the particulars of the means for powering the data carrier as set forth by the above claim. However, the particulars of the means for powering are mechanical expedients of each other.

28. As to claim 11, Wolf/Rode teaches a drug package according to claim 10, wherein the data carrier is arranged to generate a radio-frequency signal bearing the treatment information.

29. As to claim 15, Wolf/Rode teaches a drug delivery apparatus according to claim 13, wherein the input is a radio frequency input which received the treatment information from a data carrier at radio frequency.

30. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al.

31. As to claim 18, Wolf et al. teaches a drug delivery apparatus according to claim 13. It should be noted that Wolf et al. fails to teach where the drug delivery apparatus is

one of a pneumatic nebulizer, a piezo-electric nebulizer, and an ultrasonic nebulizer. However, the use of pneumatic nebulizers, piezo-electric nebulizers, or ultrasonic nebulizers is old and well known in the art of inhalers (5,685,291, 6,085,740, 5,483,953). Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Wolf et al. if the desired drug to be delivered is a liquid.

32. Claims 22-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al. in view of Eigler et al. 6,328,699.

33. As to claim 22, Wolf et al. teaches a drug deliver device comprising:

a delivery portion for delivering a drug to a patient 140;.

a drug use analyzer which analyses to amount of a drug delivered over a number of treatments and which identifies when only a certain proportion of the prescribed drug remains (col. 13, line 52-67).

It should noted that Wolf et al. fails to teach a repeat prescription ordering portion which operates to electronically order a repeat prescription once the drug use analyzer identifies that less than the certain proportion of the prescribed drug remains. However, Eigler et al. does teach a repeat prescription ordering portion which operates to electronically order a repeat prescription (col. 10, lines 60-65). Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Wolf et al. to include the repeat prescription ordering portion of Eigler et al. to ensure that the user has a new supply of the drug before the drug in the device is exhausted.

34. As to claim 23, Wolf/Eigler teaches a drug delivery device according to claim 22, wherein the repeat prescribed ordering portion includes a modem which automatically connects to a telephone system to electronically order a repeat prescription (col. 13-26).

35. As to claim 24, Wolf/Eigler teaches a drug delivery device according to claim 22, wherein the repeat prescription ordering portion includes a connection to an electronic network through which the repeat prescription is ordered (col. 10, lines 60-65).

36. As to claim 25, Wolf/Eigler teaches a drug delivery device according to claim 22, wherein the drug use analyzer includes a counter for counting the number of drug treatments delivered (col. 13, lines 52-67).

37. As to claim 26, Wolf/Eigler teaches a drug delivery device according to claim 25, wherein the drug use analyzer includes a memory for holding the total number of drug treatments that are possible from an existing course of drug treatments (col. 13, lines 52-67).

38. As to claim 27, Wolf/Eigler teaches a drug delivery device according to claim 26, wherein the drug use analyzer includes a comparitor which compared the number of drug treatments that are possible from the memory with the number of drug treatments delivered from the counter, and generates a re-order signed when only a certain proportion of the prescribed drug remains (col. 13, lines 52-67).

39. As to claim 28, Wolf/Eigler teaches a drug delivery device according to claim 27, wherein the repeat prescription re-ordering portion orders a repeat prescription once it received a re-order signed from the drug use analyzer (col. 10, lines 60-65).

40. As to claim 29, Wolf/Eigler teaches a drug delivery device according to claim 22, wherein the drug use analyzer includes a data carrier, including drug treatment information including the total number of drug treatments that are possible from an existing course of drug treatments (col. 13, line 52-67).

41. As to claim 30, Wolf/Eigler teaches a drug delivery device according to claim 29, wherein the memory for holding the total number of drug treatments is located in the data carrier (col. 13, lines 52-55).

42. As to claim 31, Wolf/Eigler teaches a method of prescribing a drug, comprising:

supplying a patient with a course of a number of drug treatments 623 for administering using a drug delivery device;

analyzing the use of the drug treatments (col. 13, lines 35-39);

identifying when only a certain proportion of the drug treatments remains (col. 13, line 52-67); and

electronically ordering a repeat prescription once it has been identified that only a certain proportion of the drug treatments remain (col. 10, lines 60-65).

43. As to claim 32, Wolf/Eigler teaches the method according to claim 31, further comprising:

issuing a course of drug treatments or a prescription for the course of treatments in response to the electronic order (col. 10, lines 60-65).

44. As to claim 33, Wolf/Eigler teaches the method according to claim 31, wherein the electronic ordering is done via a modem connection to a telephone line (col. 13, line 23-26).

45. As to claim 34, Wolf/Eigler teaches the method according to claim 31, wherein the electronic ordering is done via a connection to an electronic network (col. 10, lines 60-65).

46. As to claim 35, Wolf/Eigler teaches the method according to claim 31, wherein the analyzing of the use of the drug treatments includes counting the number of drug treatments delivered (col. 13, lines 52-67).

47. As to claim 36, Wolf/Eigler teaches the method according to claim 35, wherein the analyzing includes the comparing of the number of drug treatments delivered with the total number of treatments supplied (col. 13, lines 52-67).

48. As to claim 37, Wolf/Eigler teaches the method according to claim 31, further including the step of generating a re-order signal when it is identified that only a certain proportion of the drug treatments remain (col. 10, lines 60-65).

49. As to claim 38, Wolf/Eigler teaches the method according to claim 31, further comprising the supply of a data carrier with the course of a number of drug treatments, the data carrier bearing drug treatment information including the total number of drug treatments that are possible from the existing course of drug treatments (col. 13, lines 52-67).

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (703) 305-3285. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Aaron Lewis can be reached on (703) 308-0716. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communications and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MM
September 8, 2002

GLENN K. DAWSON
PRIMARY EXAMINER